## Food and Drug Administration, HHS

- (B) Indications for use. For the removal of large roundworms (Toxocara canis and Toxascaris leonina) and hookworms (Ancylostoma caninum and Uncinaria stenocephala).
- (C) Limitations. Additional treatment may be required and should be confirmed by fecal examination within 2 to 4 weeks
- (ii) Dogs, puppies, and lactating bitches after whelping—(A) Amount. 2.27 mg/lb body weight.
- ( $\mathring{B}$ ) *Indications for use*. To prevent reinfections of *T. canis*.
- (C) *Limitations*. Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals.

[67 FR 43248, June 27, 2002, as amended at 68 FR 54803, Sept. 19, 2003; 68 FR 55199, Sept. 23, 2003; 68 FR 55825, Sept. 29, 2003]

#### § 520.2044 Pyrantel pamoate paste.

- (a) *Specifications*. (1) Each milliliter (mL) contains 180 milligrams (mg) pyrantel base (as pyrantel pamoate).
- (2) Each mL contains 226 mg pyrantel base (as pyrantel pamoate).
- (3) Each mL contains 171 mg pyrantel base (as pyrantel pamoate).
- (b) *Sponsors*. See sponsors in §510.600(c) of this chapter.
- (1) No. 000069 for use of product described in paragraph (a)(1) of this section
- (2) No. 059130 for use of product described in paragraph (a)(2) of this section.
- (3) No. 061623 for use of product described in paragraph (a)(3) of this section.
- (c) *Conditions of use.* It is used in horses and ponies as follows:
- Amount. Equivalent of 3 milligrams pyrantel base per pound of body weight.
- (2) Indications for use. For removal and control of infections from the following mature parasites: large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); small strongyles; pinworms (Oxyuris equi); and large roundworms (Parascaris equorum).
- (3) *Limitations.* Administer as single dose by depositing paste on dorsum of the tongue using the dose syringe. Not for use in horses intended for food. It is

recommended that severely debilitated animals not be treated with this preparation. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[47 FR 47377, Oct. 26, 1982; 48 FR 3367, Jan. 25, 1983, as amended at 68 FR 13627, Mar. 20, 2003; 68 FR 34533, June 10, 2003]

# § 520.2045 Pyrantel tartrate powder; pyrantel tartrate pellets.

- (a) *Specifications.* (1) Pyrantel tartrate powder horse wormer contains 11.3 percent and swine wormer 10.6 percent pyrantel tartrate.
- (2) Pyrantel tartrate pellets colt and horse wormer contains 1.25 percent pyrantel tartrate.
- (b) Sponsor. (1) See No. 000069 in \$510.600(c) of this chapter for conditions of use provided for in paragraphs (d) (1) and (2) of this section.
- (2) See No. 051311 in §510.600(c) of this chapter, for conditions of use provided for in paragraph (d)(3) of this section.
- (c) Related tolerances. See §556.560 of this chapter.
- (d) *Conditions of use.* It is used in: (1) Horses and ponies:
- (i) For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus vulgaris, Strongylus edentatus, Strongylus equinus), small strongyles (Trichonema spp., Triodontophorus), pinworms (Oxyuris), and large roundworms (Parascaris).
- (ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.
- (iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.
- (iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.
  - (2) Swine:
- (i) For the removal and control of large roundworms (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.
- (ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted ration. The ration is administered as a single treatment as the

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sole ration at the rate of 1 pound per 40 pounds of animal weight for animals up to 200 pounds. Animals 200 pounds and over are administered 5 pounds of ration per animal.

- (iii) Fast pigs over night for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.
- (iv) Warning: Do not treat within 24 hours of slaughter.
  - (3) Horses and colts:
- (i) For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus vulgaris, Strongylus edentatus, Strongylus equinus), small strongyles (Trichonema spp., Triodontophorus), pinworms (Oxyuris), and large roundworms (Parascaris).
- (ii) It is administered as a single dose at 12.5 milligrams of pyrantel tartrate per 2.2 pounds of body weight mixed with the usual grain ration.
- (iii) It is recommended that severely debilitated animals not be treated with this drug.
- (iv) Warning: Do not use in horses or colts intended for food.
- [40 FR 13838, Mar. 27, 1975, as amended at 59 FR 28769, June 3, 1994; 69 FR 41427, July 9, 2004]

### §520.2087 Roxarsone soluble powder.

- (a) *Specifications.* Each ounce (avoirdupois) of soluble powder contains 21.7 grams of roxarsone (monosodium 3-nitro-4-hydroxyphenylarsonate).
- (b) *Sponsor*. See No. 046573 ir §510.600(c) of this chapter.
- (c) Related tolerances. See §556.60 of this chapter.
- (d) NAS/NRC status. These conditions of use are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
- (e) Conditions of use—(1) Growing chickens and growing turkeys—(i) Amount. 0.002 percent roxarsone in drinking water (one packet per each 250 gallons of drinking water).

- (ii) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation.
- (iii) *Limitations.* Administer continuously throughout growing period. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.
- (2) Swine—(i) Amount. 0.01 percent roxarsone in drinking water (one packet per each 50 gallons of drinking water); or 30 milliliters of a 1.55 percent roxarsone solution (one packet per 3 pints of water) per 50 pounds of body weight as a drench.
- (ii) *Indications for use.* As an aid in the treatment of swine dysentery (hemorrhagic enteritis or bloody scours).
- (iii) *Limitations.* Administer drinking water continuously for not more than 6 days. Administer drench once daily for 1 or 2 days. If no improvement is observed, consult a veterinarian. Treatment may be repeated after 5 days. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

[46 FR 41039, Aug. 14, 1981, as amended at 55 FR 8460, Mar. 8, 1990; 57 FR 8577, Mar. 11, 1992; 69 FR 41427, July 9, 2004]

## § 520.2088 Roxarsone tablets.

- (a)(1) Specifications. Each tablet contains 36 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).
- (2) *Sponsor*. See No. 046573 ir §510.600(c) of this chapter.
- (3) Related tolerances. See §556.60 of this chapter.
- (4) NAS/NRC status. The weight gain, feed efficiency, and pigmentation claims are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
- (5) Conditions of use—(i) Growing chickens and growing turkeys—(a) Amount. Dissolve 2 tablets in each gallon of drinking water (0.002 percent roxarsone).
- (b) Indications for use. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.
- (c) Limitations. Administer continuously throughout growing period. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.